1-14-02

Petition
OFFICE

PATENT

"Express Mail" Label No. EL140089321US
Date of Deposit January 9, 2002

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BOX PATENT EXTENSION
Commissioner for Patents
Washington, D.C. 20231

By: Daniel Miranda

TTC Docket No. 017516-007400US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent of:

Phillip S. Green

Patent No.: 5,808,665

Issued: September 15, 1998

Title: ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD FOR USE

REQUEST FOR RECONSIDERATION FOR PATENT TERM EXTENSION UNDER 35 U.S.C. § 156

Hon. Commissioner of Patents and Trademarks
Box: Patent Extension
Washington, D.C. 20231

Sir:

Applicants respectfully request reconsideration for a patent term extension of U.S. Patent No. 5,808,665. A patent term extension request was filed under 35 U.S.C. § 156 on September 11, 2000 in light of Food and Drug Administration (hereinafter "FDA") approval of the da Vinci™ Robotic Surgery System. A Final Determination of Ineligibility (hereinafter "Determination") was mailed from the Patent Office on November 14, 2001.

Dismissal of the application for the subject patent term extension was apparently based on the determination by the Commissioner of Patents and Trademarks (hereinafter "Commissioner") that the da Vinci™ System underwent regulatory review under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (hereinafter "FFDCA"). Determination, page 2. However, as properly determined by the FDA, the da Vinci™ system was subjected to a regulatory review period as defined by 35 U.S.C. §156(a)(4), including regulatory review under section 515 of the FFDCA. FDA letter dated October 2, 2001.

The regulatory review of the da Vinci™ System was conducted under both sections 515 and 510(k) of Chapter 5 of the FFDCA, with approval eventually being granted under 510(k). As the da Vinci™ System was subjected to regulatory review under section 515, Applicants are entitled to a patent term extension. Per 35 U.S.C. §156(d)(2), the Secretary of Health and Human Services is responsible for determining the Regulatory Review Period for medical devices, and this matter was properly referred to the FDA. In a preliminary eligibility decision, the FDA informed the Commissioner that a "review of the Food and Drug Administration's official records indicates that this product **was subject to a regulatory review** period before its commercial marketing or use, **as required under 35 U.S.C. § 156(a)(4).**" *Id* (Emphasis added).

Reviewing the language of the statute, 35 U.S.C. § 156(a)(4), requires that, "the product has been subject to a regulatory review period before its commercial marketing or use." For medical devices, the term "regulatory review period" is defined in § 156(g)(3)(B) as follows:

> (i) the period beginning on the date a clinical investigation on human involving the device was begun and ending on the date an application was initially submitted with respect to the device under section 515, and
>
> (ii) the period beginning on the date an application was initially submitted with respect to the device under section 515 and **ending on the date such application was approved under such Act** or the period beginning on the date a notice of completion of a product development protocol was initially submitted under section 515(f)(5) and ending on the date the protocol was declared completed under section 515(f)(6).

(Emphasis added). Therefore, within the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B), a regulatory review period begins at the initiation of human clinical trials and ends on approval under the "Act," i.e. the FFDCA, which includes both sections 515 and 510(k) of Chapter 5.

The FDA correctly verified that Applicants meet the statutory requirements for a regulatory review period under the plain language of 35 U.S.C. § 156(a)(4) and § 156(g)(3)(B). *Id.* Specifically, Applicants began their first clinical investigations on humans on July 27, 1998. On January 17, 1999 Applicants submitted a section 510(k) application

#K990144 to the FDA seeking laparoscopic approval for its da Vinci™ System. On May 19, 1999, the FDA reclassified the da Vinci™ System into a class III device requiring Pre-Market Approval (hereinafter "PMA") under section 515. Applicants complied with the FDA mandated reclassification by (a) submitting a complete PMA application #P990079 on November 18, 1999 based on the same clinical data gathered during its earlier human clinical investigations, and (b) requesting that the FDA approve the da Vinci™ System under section 515 for laparoscopic procedures. The FDA accepted the PMA application for filing on November 29, 1999. On May 22, 2000, the FDA again reclassified the da Vinci™ System so that its corresponding PMA application #P990079, which had been reviewed for over a year under section 515, was reverted back to a 510(k). On July 11, 2000, the FDA approved the 510(k) application #K990144, with the submission date marked as November 18, 1999, the date the PMA application #P990079 under section 515 was submitted to the FDA.

As a final matter, Applicants gratefully acknowledge the Patent Office's correct determination that the Patent Term Extension request was timely filed. Determination, page 1. The FDA communication raised the issue as to whether the application was timely filed within the sixty-day (60) statutory period under 35 U.S.C. § 156(d)(1). FDA letter dated October 2, 2001. While the FDA often possesses information which is not readily available to the Commissioner, the Commissioner has primary responsibility for the eligibility determination. See M.P.E.P. § 2756. The Commissioner correctly determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms. Determination, page 1. The date of product approval was July 11, 2000. The present patent term extension application was filed on Monday, September 11, 2000. Sixty days after the approval date of the product was Saturday, September 9, 2000. 35 U.S.C. § 21(b) states that

> When the day, or the last day, for taking any action or paying any fee in the United States Patent and Trademark Office falls on Saturday, Sunday, or a federal holiday within the District of Columbia, the action may be taken, or the fee paid, on the next succeeding secular or business day.

As Monday, September 11, 2000 was the next succeeding business day following the last day (Saturday, September 9, 2000), the application was timely filed.

As the FDA has verified that the present application satisfies the statutory

requirements for a regulatory review period under 35 U.S.C. § 156(a)(4) and the Commissioner has determined that the present application was timely filed within the sixty-day (60) period permitted for submission of such applications for extension of patent terms, the last day of said sixty-day (60) period being September 11, 2000, the present application qualifies for a patent term extension. For the foregoing reasons, reconsideration and granting of Applicants application for patent term extension is respectfully requested.

Respectfully submitted,

1/8/02

David M. Shaw
Reg. No. 38,688
Chief Patent Counsel
Intuitive Surgical, Inc.
Tel: (650) 237-7000
Fax: (650) 526-2060

PA 3191866 v1

Please type a plus sign (+) inside this box → [+]

PTO/SB/21 (08-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Phillip S.
Group Art Unit	
Examiner Name	
Total Number of Pages in This Submission: 7	
Attorney Docket Number	017516-007400US

ENCLOSURES *(check all that apply)*

- [x] Fee Transmittal Form
  - [ ] Fee Attached
- [ ] Amendment / Response
  - [ ] After Final
  - [ ] Affidavits/declaration(s)
- [x] Extension of Time Request
- [ ] Express Abandonment Request
- [ ] Information Disclosure Statement
- [ ] Certified Copy of Priority Document(s)
- [ ] Response to Missing Parts/ Incomplete Application
  - [ ] Response to Missing Parts under 37 CFR 1.52 or 1.53
- [ ] Assignment Papers *(for an Application)*
- [ ] Drawing(s)
- [ ] Licensing-related Papers
- [ ] Petition Routing Slip (PTO/SB/69) and Accompanying Petition
- [ ] Petition to Convert to a Provisional Application
- [ ] Power of Attorney, Revocation Change of Correspondence Address
- [ ] Terminal Disclaimer
- [ ] Request for Refund
- [ ] CD, Number of CD(s)
- [ ] After Allowance Communication to Group
- [ ] Appeal Communication to Board of Appeals and Interferences
- [ ] Appeal Communication to Group *(Appeal Notice, Brief, Reply Brief)*
- [ ] Proprietary Information
- [ ] Status Letter
- [x] Other Enclosure(s) *(please identify below)*:

Request for Reconsideration for Patent Term Extension under 35 U.S.C §156 and Return Postcard

Remarks

The Commissioner is authorized to charge any additional fees to Deposit Account 20-1430.

RECEIVED
JAN 25 2002
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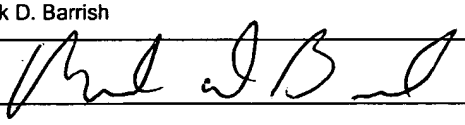
DEPUTY A/C PATENTS

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm and Individual name	Townsend and Townsend and Crew LLP Mark D. Barrish Reg. No. 36,443
Signature	
Date	January 9, 2002

CERTIFICATE OF MAILING

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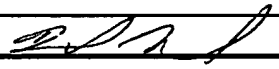
Assistant Commissioner for Patents, Washington, D.C. 20231

Typed or printed name	Daniel Miranda		
Signature		Date	January 9, 2002

PTO/SB/22 (10-00)
Approved for use through 10/31/2002. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PETITION FOR EXTENSION OF TIME UNDER 37 CFR 1.136(a)

Docket Number (Optional): 017516-007400US

In re Application of PHILLIP S. GREEN	
Application Number 08/709,965	Filed September 9, 1996
For ENDOSCOPIC SURGICAL INSTRUMENT AND METHOD OF USE	
Group Art Unit	Examiner

This is a request under the provisions of 37 CFR 1.136(a) to extend the period for filing a reply in the above identified application.

The requested extension and appropriate non-small-entity fee are as follows (check time period desired):

☒	One month (37 CFR 1.17(a)(1))	$110
☐	Two months (37 CFR 1.17(a)(2))	$
☐	Three months (37 CFR 1.17(a)(3))	$
☐	Four months (37 CFR 1.17(a)(4))	$
☐	Five months (37 CFR 1.17(a)(5))	$

☒ Applicant claims small entity status. See 37 CFR 1.27. Therefore, the fee amount shown above is reduced by one-half, and the resulting fee is: $ 55 .

☐ A check in the amount of the fee is enclosed.

☐ Payment by credit card. Form PTO-2038 is attached.

☐ The Commissioner has already been authorized to charge fees in this application to a Deposit Account.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment, to Deposit Account Number 20-1430.

I have enclosed a duplicate copy of this sheet.

I am the ☐ applicant/inventor.

☐ assignee of record of the entire interest. See 37 CFR 3.71

Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96).

☒ attorney or agent of record.

☐ attorney or agent under 37 CFR 1.34(a).

Registration number if acting under 37 CFR 1.34(a). _____ .

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

January 9, 2002
Date

Signature

Mark D. Barrish, Reg. No. 36,443
Typed or printed name

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

PA 3194286 v1

PTO/SB/17 (09-00)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2001

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT ($) 55

Complete If Known	
Application Number	08/709,965
Filing Date	September 9, 1996
First Named Inventor	GREEN, Philip S.
Examiner Name	
Group Art Unit	
Attorney Docket No.	017516-007400US

METHOD OF PAYMENT

1. ☒ The Commissioner is hereby authorized to charge indicated fees and credit any over payments to:

Deposit Account Number: 20-1430

Deposit Account Name: Townsend and Townsend and Crew LLP

☒ Charge Any Additional Fee Required Under 37 CFR 1.16 and 1.17

☒ Applicant claims small entity status. See 37 CFR 1.27

2. ☐ **Payment Enclosed:**

☐ Check ☐ Credit card ☐ Money Order ☐ Other

FEE CALCULATION

1. BASIC FILING FEE

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($)

2. EXTRA CLAIM FEES

			Extra Claims		Fee from below	=	Fee Paid
Total Claims		-20**	=	X		=	
Independent Claims		-3**	=	X		=	
Multiple Dependent				X		=	

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim, if not paid
109	84	209	42	** Reissue independent claims over original patent
110	18	210	9	** Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($)

**or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Fee Code	Large Entity Fee ($)	Small Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet.	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	55
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive – unavoidable	
141	1,280	241	640	Petition to revive – unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	50	123	50	Petitions related to provisional applications	
126	180	126	180	Submission of Information Disclosure Stmt	
581	40	581	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR § 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR § 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify)					

The Commissioner is authorized to charge any additional fees to the above noted Deposit Account.

*Reduced by Basic Filing Fee Paid SUBTOTAL (3) ($)55

SUBMITTED BY				Complete (if applicable)	
Name (Print/Type)	Mark D. Barrish	Registration No. (Attorney/Agent)	36,443	Telephone	650-326-2400
Signature				Date	January 9, 2002

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